

WHAT IS CLAIMED IS:

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1. A method of sterilizing and/or sanitizing a container, said method comprising the steps of:

generating a sterilant vapor;

positioning a nozzle through an opening in the container and to a position no closer than 15 mm from any internal surface of the container that is perpendicular to a principal direction of flow of sterilant vapor from the nozzle;

discharging the generated sterilant vapor through the nozzle and into the container; and

purging the container of the discharged sterilant.

2. A method according to Claim 1, wherein after said positioning step, the nozzle is positioned no closer than 15 mm from the bottom of the container.

3. A method according to Claim 1, wherein the container comprises a shoulder below the opening and in said positioning step the nozzle is positioned just below the shoulder.

4. A method according to Claim 1, wherein after said positioning step, the nozzle is inserted within $1/6$ and $5/6$ the height of the container.

5. A method according to Claim 1, wherein the sterilant comprises hydrogen peroxide.

6. A method according to Claim 1, further comprising the step of heating the nozzle.

7. A method according to Claim 1, wherein the container is formed at least in part of PET.

8. A method according to Claim 1, wherein said purging step comprises forcing heated gas into the container through the nozzle.

9. A method according to Claim 1, wherein the nozzle has a diameter no greater than one-half the diameter of the opening of the container.

10. A method according to Claim 1, wherein the sterilant vapor used in said discharging step and a gas used in said purging step are at temperatures no greater than 160° F.

11. A method according to Claim 1, wherein said purging step is effected no longer than 30 seconds from said discharging step.

12. A method according to Claim 1, further comprising the step of positioning the nozzle above the opening of the container and discharging the sterilant vapor onto the exterior of the container.

5 13. A method of sterilizing and/or sanitizing a container, the container having an opening of a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening being at least 7.5, said method comprising the steps of:

generating a sterilant vapor;

10 positioning a nozzle through the opening in the container, the nozzle having a diameter no greater than one-half the predetermined diameter of the opening of the container;

discharging the generated sterilant vapor through the nozzle and into the container; and

purging the container of the discharged sterilant.

15 14. A method according to Claim 13, wherein the sterilant comprises hydrogen peroxide.

15. A method according to Claim 13, further comprising the step of heating the nozzle.

16. A method according to Claim 13, wherein the container is formed at least in part of PET.

17. A method according to Claim 13, wherein said purging step comprises forcing heated gas into the container through the nozzle.

18. A method according to Claim 13, wherein after said positioning step, the nozzle is disposed no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow from the nozzle.

19. A method according to Claim 13, wherein after said positioning step the nozzle is inserted within $1/6$ and $5/6$ the height of the container.

20. A method according to Claim 13, wherein the sterilant vapor used in said discharging step and a gas used in said purging step are at temperatures no greater than 160°F .

21. A method according to Claim 13, wherein said purging step is effected no longer than 30 seconds from said discharging step.

22. A method according to Claim 13, further comprising the step of positioning the nozzle above the opening of the container and discharging the sterilant vapor onto the exterior of the container.

23. A method according to Claim 13, wherein the predetermined diameter of the opening of the container is no more than one-half the maximum diameter of the container.

24. A method of sterilizing and/or sanitizing a PET container, said method comprising the steps of:

generating a sterilant vapor having a temperature no greater than 160° F;

positioning a nozzle through an opening in the container;

discharging the generated sterilant vapor through the nozzle and into the container; and

purging the container of the discharged sterilant with a heated gas having a temperature no greater than 160° F, wherein said purging step is completed no longer than 30 seconds from a beginning of said discharging step.

25. A method according to Claim 24, wherein the sterilant comprises hydrogen peroxide.

26. A method according to Claim 24, further comprising the step of heating the nozzle.

27. A method according to Claim 24, wherein the container is formed in part of PET.

28. A method according to Claim 24, wherein in said purging step, the heated gas is discharged into the container through the nozzle.

29. A method according to Claim 24, wherein in said positioning step, the nozzle is disposed no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow from the nozzle.

30. A method according to Claim 24, wherein after said positioning step the nozzle is inserted within $1/6$ and $5/6$ the height of the container.

31. A method according to Claim 24, wherein the opening of the container has a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening is at least 7.5, and the nozzle has a diameter no greater than one-half the predetermined diameter of the opening of the container.

32. A method according to Claim 24, further comprising the step of positioning the nozzle above the opening of the container and discharging the sterilant vapor onto the exterior of the container.

33. An apparatus for sterilizing and/or sanitizing a container, said apparatus comprising:

a generator of sterilant vapor;

a nozzle communicating with said generator;

a positioning mechanism for positioning said nozzle through an opening in the container and to a position no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow of sterilant vapor from the nozzle; and

a controller for controlling discharging of the generated sterilant vapor through said nozzle and into the container and purging of the container of the discharged sterilant.

34. An apparatus according to Claim 33, wherein said positioning mechanism positions the nozzle no closer than 15 mm from the bottom of the container.

35. An apparatus according to Claim 33, wherein the container comprises a shoulder below the opening and said positioning mechanism positions said nozzle just below the shoulder.

36. An apparatus according to Claim 33, wherein said positioning mechanism inserts the nozzle within $1/6$ and $5/6$ the height of the container.

37. An apparatus according to Claim 33, wherein the sterilant comprises hydrogen peroxide.

38. An apparatus according to Claim 33, further comprising a heater for heating said nozzle.

39. An apparatus according to Claim 33, wherein the container is formed at least in part of PET.

40. An apparatus according to Claim 33, wherein in purging, said controller controls forcing of heated gas into the container through said nozzle.

41. An apparatus according to Claim 33, wherein the opening of the container has a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening is at least 7.5, and said nozzle has a diameter no greater than one-half the diameter of the opening of the container.

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42. An apparatus according to Claim 33, wherein said controller controls the sterilant vapor and a purge gas to be at temperatures no greater than 160° F.

43. An apparatus according to Claim 33, wherein said controller controls purging to be effected no longer than 30 seconds from discharging of the sterilant.

44. An apparatus according to Claim 33, wherein said controller further controls positioning of the nozzle above the opening of the container and discharging of the sterilant vapor onto the exterior of the container.

45. An apparatus for sterilizing and/or sanitizing a container, the container having an opening of a predetermined diameter, a the ratio of the interior surface area of the container to the cross-sectional area of the opening being at least 7.5, said apparatus comprising:

a generator of sterilant vapor;

a nozzle communicating with said generator, said nozzle having a diameter no greater than one-half the predetermined diameter of the opening of the container;

a positioning mechanism for positioning said nozzle through the opening in the container; and

a controller for controlling discharging of the generated sterilant vapor through said nozzle and into the container and purging of the container of the discharged sterilant.

5 46. An apparatus according to Claim 45, wherein the sterilant comprises hydrogen peroxide.

 47. An apparatus according to Claim 45, further comprising a heater for heating said nozzle.

 48. An apparatus according to Claim 45, wherein the container is formed at least in part of PET.

10 49. An apparatus according to Claim 45, wherein in purging, said controller controls forcing of heated gas into the container through said nozzle.

 50. An apparatus according to Claim 45, wherein said positioning mechanism positions said nozzle no closer than 15 mm from any internal surface of the container that is perpendicular to the direction of flow from the nozzle.

15 51. An apparatus according to Claim 45, wherein said positioning mechanism inserts the nozzle within $1/6$ and $5/6$ of the height of the container.

52. An apparatus according to Claim 45, wherein said controller controls the sterilant vapor and a flush gas to be at temperatures no greater than 160° F.

53. An apparatus according to Claim 45, wherein said controller controls purging to be effected no longer than 30 seconds from discharging of the sterilant.

54. An apparatus according to Claim 45, wherein said controller further controls positioning of the nozzle above the opening of the container and discharging of the sterilant vapor onto the exterior of the container.

55. An apparatus according to Claim 45, wherein the predetermined diameter of the opening of the container is no more than one-half the maximum diameter of the container.

56. An apparatus for sterilizing and/or sanitizing a PET container, said apparatus comprising:

a generator of sterilant vapor having a temperature no greater than 160° F;

a nozzle communicating with said generator;

a positioning mechanism for positioning said nozzle through an opening in the container; and

a controller for controlling discharging of the generated sterilant vapor through said nozzle and into the container and purging of the container of the discharged sterilant with a heated gas having a temperature no greater than 160° F, wherein said controller controls purging to be completed no longer than 30 seconds from discharging of the sterilant.

57. An apparatus according to Claim 56, wherein the sterilant comprises hydrogen peroxide.

58. An apparatus according to Claim 56, further comprising a heater for heating said nozzle.

59. An apparatus according to Claim 56, wherein the container is formed at least in part of PET.

60. An apparatus according to Claim 56, wherein in purging, said controller controls forcing of the heated gas into the container through said nozzle.

61. An apparatus according to Claim 56, wherein said positioning mechanism positions said nozzle to a position no closer than 15 mm from any internal surface of the container that is perpendicular to a principle direction of flow of sterilant vapor from the nozzle.

62. An apparatus according to Claim 56, wherein said positioning mechanism inserts the nozzle within 1/6 and 5/6 the height of the container.

63. An apparatus according to Claim 56, wherein the opening of the container has a predetermined diameter, a ratio of the interior surface area of the container to the cross-sectional area of the opening is at least 7.5, and said nozzle has a diameter no greater than one-half the diameter of the opening of the container.

64. An apparatus according to Claim 56, wherein said controller further controls positioning of the nozzle above the opening of the container and discharging of the sterilant vapor onto the exterior of the container.

65. A method of sterilizing and/or sanitizing a container, said method comprising the steps of:

generating hydrogen peroxide sterilant vapor;

discharging the generated sterilant vapor into the container; and

purging the container of the discharged sterilant with heated gas,

wherein reduction of Bacillus spores in the container by a predetermined amount X (log) is effected by satisfying the following equation

$$X = (0.138 \times a/b) + (0.066 \times T_1) - (0.00083 \times c/b) + (0.021 \times T_2) + (0.008347 \times d) - 11.357,$$

wherein a is the mass of discharged sterilant vapor (mg),

b is the container volume (l),

c is the volume of purging gas (l),

d is the ambient relative humidity (%RH),

T₁ is the temperature of the discharged sterilant vapor (°F), and

T₂ is the temperature of the purging gas (°F).

66. A method according to Claim 65, wherein the spores are Bacillus subtilis var. globigii.

67. A method according to Claim 65, wherein the predetermined reduction amount (X) of the spores in the container equals at least 6 log.

68. A method according to Claim 65, wherein the residual sterilant is reduced in said purging step to a desired level (Z) (mg/l) by satisfying the following equation:

$$Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.747.$$

69. A method according to Claim 65, wherein the sterilant comprises 35% hydrogen peroxide.

70. A method of sterilizing and/or sanitizing a container, said method comprising the steps of:

generating a hydrogen peroxide sterilant vapor;
discharging the generated sterilant vapor into the container; and
purging the container of the discharged sterilant with heated gas,
wherein reduction of yeast ascospores in the container by a predetermined amount
5 Y (log) is effected by satisfying the following equation

$$Y = (0.063 \times a/b) + (0.023 \times T_1) - (0.00036 \times c/b) + (0.052 \times T_2) + (0.009 \times d) - 3.611,$$

wherein a is the mass of discharged sterilant vapor (mg),

b is the container volume (l),

c is the volume of purging gas (l),

d is the ambient relative humidity (%RH),

T₁ is the temperature of the discharged sterilant vapor (°F), and

T₂ is the temperature of the purging gas (°F).

71. A method according to Claim 70, wherein the ascospores are
15 of the yeast Saccharomyces cerevisiae.

72. A method according to Claim 70, wherein the predetermined
reduction amount (Y) of the ascospores in the container equals at least 5 log.

73. A method according to Claim 70, wherein the residual
sterilant is reduced in said purging step to a desired level (mg/l) (Z) by satisfying
20 the following equation:

$$Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) + 15.74.$$

74. A method according to Claim 70, wherein the sterilant comprises 35% hydrogen peroxide.

75. A method of sterilizing and/or sanitizing a container, said method comprising the steps of:

generating hydrogen peroxide sterilant vapor;

discharging the generated sterilant vapor into the container; and

purging the container of the discharged sterilant with heated gas,

wherein reduction of the sterilant in the container to a predetermined amount Z (mg/l) is effected by satisfying the following equation

$$Z = (0.030 \times a/b) - (0.043 \times T_1) - (0.040 \times c/b) - (0.075 \times T_2) +$$

15.747,

wherein a is the mass of discharged sterilant vapor (mg),

b is the container volume (l),

c is the volume of purging gas (l),

T₁ is the temperature of the discharged sterilant vapor (°F), and

T₂ is the temperature of the purging gas (°F).

76. A method according to Claim 75, wherein the sterilant comprises 35% hydrogen peroxide.

77. A method according to Claim 75, wherein the predetermined amount is 0.5 mg/l at 24 hours after said purging step.

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